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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 10/606,300  | 06/25/2003  | Danilo Porro         | 2027.594097/RFE<br>(2005942) | 8974             |
| 23720   | 7590        | 10/06/2006           |                              | EXAMINER         |
| WILLIAMS, MORGAN & AMERSON<br>10333 RICHMOND, SUITE 1100<br>HOUSTON, TX 77042 |             |                      | SCHLAPKOHL, WALTER           |                  |
|   |             |                      | ART UNIT                     | PAPER NUMBER     |
|   |             |                      | 1636                         |                  |

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                             |  |
|------------------------------|------------------------|-----------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>         |  |
|                              | 10/606,300             | PORRO ET AL.<br><i>luay</i> |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>             |  |
|                              | Walter Schlapkohl      | 1636                        |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 18 July 2006.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 12-14 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 12-14 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

Receipt is acknowledged of the papers filed 7/18/2006.

Claims 12-14 are pending.

***Specification***

Applicant's amendment to the specification is sufficient to obviate the objection to the specification. The objection to the disclosure is hereby WITHDRAWN.

***Claim Objections***

The claims have been provided with the proper status identifiers. The objection to the claims for lacking proper status identifiers is hereby WITHDRAWN.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description

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requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record set forth in the Office action mailed 12/6/2005.**

*Response to Arguments*

Applicant argues that the claims recite, among other features, proteins having both the functional characteristics of an LGDH enzyme, i.e. NAD<sup>+</sup>-dependent enzyme catalysis of L-galactose to L-galactono-1,4-lactone, and a structural characteristic, i.e. a structure having at least about 90% similarity or identity to SEQ ID NO: 11 or encoded by a coding region having a structure having at least about 90% identity with SEQ ID NO: 12. Applicant argues that both the functional characteristic and the structural characteristic of an LGDH enzyme are clear to the skilled artisan and are described in the specification in a way that reasonably conveys to the skilled artisan that Applicant had possession of the claimed invention at the time of filing. Applicant further argues that reciting every specific protein meeting both the functional characteristics and the structural characteristics of the claims

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would be both "unduly prolix and unnecessary" (see page 6, 3<sup>rd</sup> full paragraph of the Remarks filed 7/18/2006). Applicant further argues that the skilled artisan can routinely determine whether a particular protein having the recited structural characteristic also has the recited functional characteristic, or vice versa. Applicant further argues that a lack of teachings in the specification or the prior art with regard to motifs characterizing LGDHs is irrelevant. Applicant further argues that the claims do NOT encompass deleterious variations of SEQ ID NO: 11 or SEQ ID NO: 12, i.e., such enzymes having or being encoded by such hypothetical variations which do not enable a yeast expressing the enzyme to produce ascorbic acid when grown in a medium containing an ascorbic acid precursor.

Applicant's arguments have been carefully considered but are respectfully found unpersuasive. Applicant's argument that both the structural and functional characteristics of the claimed LGDH enzymes are clear to one of ordinary skill in the art is not persuasive because one of ordinary skill in the art would not know which embodiments encompassed within the genus of enzymes with 90% identity or with 90% similarity to SEQ ID NO: 11 or encoded by a coding region having 90% identity to SEQ ID NO: 12 would be functional in a method of making ascorbic acid. Applicant's recited structural and functional characteristic

merely provide an invitation to conduct experiments to determine which sequences within the claimed genus would meet the functional criteria recited in the claims. To that end, prior knowledge or disclosure of knowledge in the specification with regard to structural motifs or other functional LGDH structures is indeed very pertinent, since such structures or motifs would provide a basis for claims of possession of LGDH structures with 90% identity and/or 90% similarly which are capable of meeting the functional requirements of the claims. Finally, while it is true that Applicant's claims do not encompass deleterious variants which are not capable of being expressed in yeast such that ascorbic acid is produced when the transformed yeast are grown in a medium containing an ascorbic acid precursor, the question of written description involves possession. Which variants of SEQ ID NO: 11 and 12, if any, does Applicant possess that are NOT deleterious variants with regard to LGDH function? Furthermore, because the art at the time of Applicant's filing is silent with regard to relevant, identifying characteristics of LGDH enzymes, one of ordinary skill in the art would not know which variants are or are NOT deleterious. Thus, given the lack of prior art on LGDH enzyme sequences, including functional motifs and other identifying characteristics, the disclosure of one representative LGDH amino acid sequence and its

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corresponding nucleic acid sequence in the specification is not sufficient to lead one of ordinary skill in the art to the genus of LGDH enzymes with at least about 90% identity/similarity to SEQ ID NOS: 11 and 12 such that, when transformed into yeast, the resulting yeast is capable of generating ascorbic acid when cultured in a medium comprising an ascorbic acid precursor.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 12-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 11-14 of copending Application No. 10/606,302.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. **This rejection is maintained for reasons of record set forth in the Office action mailed 12/6/2005.**

Claims 12-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,630,330. **This rejection is maintained for reasons of record set forth in the Office action mailed 5/23/2006.**

#### *Response to Arguments*

Applicant argues that a terminal disclaimer over US 10/606,302 and US Patent 6,630,330 have been submitted and that the basis for the rejection has been removed.

Applicant's arguments have been carefully considered, but no terminal disclaimer over US 10/606,302 and US Patent 6,630,330 has been received. Therefore, the rejections stand.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 12-14 under 35 U.S.C. 102(b) as being anticipated by Smirnoff et al (WO 99/33995) is hereby WITHDRAWN.

*Response to Arguments*

The response to Applicant's arguments regarding the rejection of claims 12-14 under 35 U.S.C. 102(b) is rendered moot due to Examiner's withdrawal of the rejection.

*Conclusion*

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS

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of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-

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9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.  
Patent Examiner  
Art Unit 1636

September 26, 2006

  
NANCY VOGEL  
PRIMARY EXAMINER